| INFORMATION DISCLOSURE | | | ATTY, DOCKET NO. | | | SERIAL NO. 09/940,422 | | | | | |
|--------------------------------|------------------------|---|--|----------------------|---|--------------------------|----------------------|---------------|------------------------|---|--|
| CITATION | | 1430-272 | | | 09/94 | | | | | | |
| | | | APPLICA | ANT | | | | | | | |
| | | | EDM | EADES | | | | | | | |
| (Use several sheets mecessary) | | | | FILING DATE | | | GROUP | | | | |
| | | | ۸.,,,,, | August 29, 2001 | | 17/13 | 1743 | | | | |
| | | DEC 1 8 2003 E | Augu | 81 29, 2001 | | 1743 | | | | | |
| | | \s. \s. \s. | / | .S. PATENT DO | CUMENTS | | | | | | |
| AMINER | | TruncMART | | .O. 1 A1 E1(1 DO | | | | | | G DATE | |
| VITIAL | г т | DOCUMENTAL MER | 8/1978 | V. | NAME lenk et al | | CLASS | SUBCLASS | IF APPR | OPRIATE | |
| 98 | | 4,108,877 | 7/1986 | - | wyer et al | | | | - 4 | vecor | |
| | \Box | 4,002,017 | 7/1700 | | wyci ci ai | | | | - 4 | VCC | |
| | \vdash | | | | | | | | | | |
| | _ | | FOR | EIGN PATENT | OCUMENTS | | | | | | |
| | | | | | | | CI 400 | CUBO! ACC | | SLATION | |
| | | DOCUMENT | DATE | C | OUNTRY | | CLASS | SUBCLASS | YES | NO NO | |
| | - | 0 247 892 B1 | 4/1991 | | ED ED | | | | | - 01 | |
| af | \vdash | 0 021 121 0 059 987 | 6/1983 | | EP EP | | | | | | |
| al I | | | 8/1985 1/1997 | | PCT | | | | | | |
| is | $\vdash \vdash$ | WO 97/00681 | 7/1997 7/1996 | | PCT | | | | | John . | |
| 00 | | WO 96/17611 | 6/1996 | | PCT | | | | | 751-17 | |
| Ws | | | | cluding Author, | | rtinent n | ages, et | lc.) | l | | |
| 38 | 1 P | PEC Update, February 1 | | | | | | | | | |
| 4/2 | | Preassi et al, "Quantitati | ve Analysis | of Lamotrigine in I | Plasma", Journ | nal of AO | AC Intern | ational, Vol. | . 79, No . | 6, 1996, | |
| · . | þ | pages 1277-1280 (| of veco | vd | | | | | | | |
| | | Quaglia et al, "Determin | ation of chlo | rthalidone and Its I | mpurities", Jo | ournal of C | Chro mato | graphy, 436 | (1963) 4 | 35-439. () | |
| | | DeAngelis et al, "Quanti | tation of the | Anticonvulsant Cir | nromide", Jou | rnal of Ch | romatogr | aphy, 721.(1 | 980) 35 | 3-360. √ ∱ | |
| as | • | Organic Synthesis, Collective Volume I, being a Revised Edition of Annual Volumes I-IX, pages 146-149, Henry | | | | | | | | | |
| | | Gilman, Editor in Chief, John Wiley & Sons Publisher, © 1941; ISBN 471 30030 6. Organic Synthesis, Collective Volume 2, being a Revised Edition of Annual Volumes X-XIX, Edited by A. H. Blatt, John | | | | | | | | | |
| is | · v | Wiley & Sons Publisher, © 1943, pages 10-13. | | | | | | | | | |
| | | Organic Synthesis, Collective Volume 3, being a Revised Edition of Annual Volumes 20-29, E.C. Horning, Editor in | | | | | | | | | |
| 68 | Ιk | Chief, John Wiley & Sons Publishers, © 1955, pages 660-663; ISBN 047 409537. Papadoyannis et al, "Solid-Phase Extraction Study and RP-HPLC", Journal of Liquid Chromatography, 18(13), 2593 | | | | | | | | | |
| | | | | raction Study and I | кР-НР СС", Ј с | ournal of I | aquid Ch | romatograph | 1 y, 18(1 3 | y, 2393— | |
| | | Sinz et al, "Isolation and | <u>€ cc√O</u> Characteriza | ation of a Novel | ". Drug Metaholi | ism and D | isposition | ı. Vol. 19. N | o. 1. © 1 | 991 bv | |
| il | i h | The American Society for | or Pharmacol | ogy and Experimen | ntal Therapeutics | s, pages 14 | 19-153. | | | | |
| | F | oig et al, "Use of Ther | mospray Liqu | uid Chromatograph | y-mass", Jou | mal of Ch | romatogr | aphy, 554 (1 | 991) 181 | 1-189.0F1 | |
| 25 | | Cooper et al, "Simultane | ous determin | nation of lamotrigin | ne", Journal of | f Chromat | ography I | 3, 702 (1997 | <u>) 22</u> 7-23 | 33. | |
| | 1 | ICH Harmonised Tripartite Guideline, Impurities in New Drug Substances, International Conference on Harmonisation of | | | | | | | | | |
| | | Technical Requirements for Registration of Pharmaceuticals for Human Use, Tables of Contents, pages 1-10, | | | | | | | | | |
| S | <u> </u> | Recommended for Adoption at Step 4 of the ICH Process on March 30, 1995. ICH Harmonised Tripartite Guideline, Impurities in New Drug Substances, International Conference on Harmonisation of | | | | | | | | | |
| S | l h | Technical Requirements for Registration of Pharmaceuticals for Human Use, Tables of Contents, pages 1-11, | | | | | | | | | |
| 18 | I I | l'echnical Requirements | Recommended for Adoption at Step 4 of the ICH Process on February 7, 2002. | | | | | | | | |
| S | i h | Recommended for Adop | tion at Step 4 | TOI THE TELL LICES. | ss our reordary 1, | | C | 1 | | c- Lalen | |
| is | I F | Recommended for Adop Rote List 1998, Rote Lis | t GmbH, Dec | ccmber 1997 / | Vo transla | tow a | exo | GNGTON | 1 00 | rejtugn | |
| 18 | I F | Recommended for Adop Rote List 1998, Rote Lis Analysis conducted by A | t GmbH, Dec | ccmber 1997 / | Vo transla | Lamotri | gine Impu | rity Profilin | g by LC | -MS and | |
| is is | 1 R 2 1 | Recommended for Adop Rote List 1998, Rote Lis | t GmbH, De Agrobiogen o | n lamotrigine table | Vo tra ns la; ets. Annexure – I | I, Lamotri | gine Impl | rity Profilin | g by LC | -MS and | |

*Examiner Wiley Sodinguis Date Considered 2/29/04

Examiner: Initial if reference considered, whether or per citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.